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| 09/771,009 | 01/25/2001 | Steven P. Holzberg | 00801.0172.00US00 | 6352 |

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10/03/2003

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| EXAMINER |
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HELMER, GEORGIA L

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| ART UNIT | PAPER NUMBER |
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1638

DATE MAILED: 10/03/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,009

Applicant(s)

HOLZBERG ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 20 June 2003, paper number 12. Applicant has cancelled claims 31-57 and 59-67, and amended claims 1-16, 21, 25, 27 and 58. Claims 1-30 and 58 are pending, and are examined in the instant action.
2. All rejections not addressed below have been withdrawn.
3. This action is made Final, necessitated by Applicant's amendments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

5. A signed copy of Applicant's IDS form 1449, Paper No. 13 filed 20 June 2003, is included.

Claim Rejections - 35 USC § 112-second

6. Claims 10, 13, 14, 17, 18, 19, 20 remain rejected under 35 U.S.C. 112, second paragraph. The claim numbers of the dependent claims is included to clearly designate the rejected claims.

In claim 10, the viral protein "gamma-b" is a shorthand name and does not tell what the protein is or where it comes from. The metes and bounds of this claim are not defined.

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In claim 13, 14, 17-20, the viral protein "beta-b" is a shorthand name and does not tell what the protein is or where it comes from. The metes and bounds of this claim are not defined.

Applicant traverses, stating primarily that these abbreviations are commonly used by one of skill in the art, and that the nomenclature clearly indicates the coding position of the protein as well as the RNA genome from which it is derived. Applicant further asserts that the information (about what it is and where it comes from) is inherent in the name itself and readily understood by one of skill in the art.

Applicant's traversal has been considered and is unpersuasive because no specific virus is named in these claims, which are drawn to a viral protein, where the protein is gamma-b or beta-b. See Written Description below.

Claim Rejections - 35 USC § 112, first paragraph

Written description

7. Claims 1-6, 8-30 and 58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to an autoproteolytic peptide comprising not more than 20 amino acids. There is no structural description, of what comprises an autoproteolytic

peptide, and there is no functional requirement or description. Applicants are claiming a genus of sequences, yet there is no description of the structural features or the functional features that define the genus. Applicant can obviate this rejection by amending this claim to recite "an autoproteolytic peptide from a foot and mouth disease virus".

Claims 10, 13, 14, and 17-20 are drawn to a polynucleotide of Claim 1, where the viral protein is "gamma b" or "beta b", respectively. There is no structural description, of what comprises gamma b" or "beta b", and there is no functional requirement, source, or description. Applicants are claiming a genus of sequences, yet there is no description of the structural features or the functional features that define the genus.

Applicant traverses, stating primarily that these abbreviations are commonly used by one of skill in the art, and that the nomenclature clearly indicates the coding position of the protein as well as the RNA genome from which it is derived. Applicant further asserts that the information (about what it is and where it comes from) is inherent in the name itself and is readily understood by one of skill in the art.

Applicant traverses, stating primarily (p. 7) that as provided in the specification at page 24, lines 19-20, the term beta-b refers to an RNA-beta encoded 60 kD disease specific protein having a nucleotide binding motif similar to an RNA -alpha encoded protein alpha-a. Applicant further asserts that the term gamma-b refers to an RNA-gamma encoded 17 kD cysteine rich protein (specification, p 24, lines 29-30).

Applicant's traversal has been considered and is unpersuasive The specifics of these terms from the specification cited above *refer to a specific virus*, the BSMV virus. These terms are not described in general.

Applicant's traversal has been considered and is not persuasive because the limitations of the specification, unless stated in the claims, are not read into the claims.

Claim Rejections - 35 USC § 103

8. Claim 1-4, 7, 9-12, 15, 16, 19, 20, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donnelly, in view of Choi, et al, Plant Journal, 2000, 23, 547-555 (See IDS).

Donnelly teaches a polynucleotide encoding a promoter (p 15-16, Figure 2, see PTG 393, in plasmid constructs) operatively linked to a transcriptional unit, wherein the transcription units encodes a fusion protein, wherein the fusion protein comprises (1) a viral protein, (2) a protein of interest, and (3) an autoproteolytic peptide, wherein (3) is fused between (1) and (2), (p 15-16, Figure 2, see PTG 393, in plasmid constructs).

Donnelly also teaches a viral protein from an RNA virus, and an autoproteolytic peptide comprising a 2A autoproteolytic peptide (p 16, Figure 2 legend).

Donnelly does not teach plant viruses and monocot plants.

Choi teaches a single-stranded plant RNA virus (p 548, column 2), a promoter functional in a plant (p 549, 1st and 2nd full ¶s) where the virus is capable of systemic expression (p 548, column 2), a plant cell infected with the recombinant virus (p552,

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Figure 4 and Table 6), and monocot plant cells and plants expressing foreign genes from this virus (p552, Figure 4 and Table 6).

One skilled in the art would have been motivated at the time of the invention to substitute for the FMDV of Donnelly the virus of Choi with a reasonable expectation of success. Motivation for this was the knowledge that RNA plant viruses could express foreign genes in monocots but that these viruses did not spread systemically, and that such systemic movement and expression of the virus and foreign genes was desirable, as taught by Choi (p 547, column 1).

The use of two viral proteins, use of N-terminal and C-terminal fusion proteins and the relative orientation of the autoproteolytic peptide, a plant structural protein and a plant cell infected with the recombinant virus are obvious variants and reflect design choices, which were well within the knowledge and skill of one of ordinary skill in the art and could be used with reasonable expectation of success. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made. Accordingly, the claimed invention is prima facie obvious in view of the prior art.

Applicant traverses, stating primarily that the cited art does not teach the claims of the present invention.

Applicant's traversal has been considered and is unpersuasive because even though Donnelly does not teach a promoter functional in a plant or plant cell, Choi teaches promoter functional in a plant or plant cell (p 549, 1st and 2nd full ¶s.)

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Applicant traverses, stating primarily (response p. 9) that there is not motivation to combine Donnelly with Choi . Applicant asserts that Choi was allegedly successful in developing a WSMV based gene vector capable of systemic infection of foreign genes, and that therefore Choi does not provide any motivation to develop a further gene vector.

Applicant's traversal has been considered and is unpersuasive. Choi does in fact provides strong motivation to develop a further gene vector. Choi says that "WSMV-based vector should be particularly useful or applications to determine the biological properties by gain-of-function assays, without the need for plant transformation" (p 553, last 2 sentences in 1st column).

Furthermore, the evidence for nonobviousness should be commensurate with the scope of the claims.

Remarks

9. No claim is allowed.
10. SEQ ID NO: 1 is known in the prior art.
11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

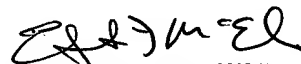
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner,
Art Unit 1638
October 1, 2003




ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600